UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,777	09/15/2003	Hassan Ahmad	2551-1-001	1508

23565 7590 09/07/2005

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,777	AHMAD ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *11-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment of July 1, 2005 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10 are examined only in regard to the elected species of *Nicotiana sativa*.

Declaration

The declaration filed July 1, 2005 has been considered.

Claim Rejections - 35 USC § 112

Claims 1, 3-10 rejected under 35 U.S.C. 112, first paragraph, have been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-6, 8-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Medenica (US 5,653,981) for the reasons set forth in the previous Office action.

Medenica (US 5,653,981) teaches using an extract of *Nigella sativa* for increasing the immune system function. Medenica also teaches how to administer the extract of *Nigella sativa* such as intramuscular, subcutaneous, intravenous, tablet, capsule or suppositories or the like. The teaching of Medenica meets the limitations of claims 1, 2, 4-10 as *Nigella sativa* and thus anticipates the claimed invention. Applicant's arguments filed July 1, 2005 have been fully considered but they are not persuasive.

Applicant argues that the product of Medenica does not teach administering the *Nicotiana sativa* for the same reasons as claimed. This is not persuasive, as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Therefore, the rejection is proper and is maintained.

Claims 1, 2, 5, 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shawkat (US 5,648,089) for the reasons set forth in the previous Office action.

Shawkat (US 5,648,089) teaches using *Nigella sativa* in an oral herb composition to treat patients diagnosed with active Hepatitis-B and Hepatitis-C (column 1, lines 20-35, 60 and claim 1). The teaching of Shawkat meets the limitations of claims 1, 2, 4 and thus anticipates the claimed invention. Applicant's arguments filed July 1, 2005 have been fully considered but they are not persuasive.

Applicant argues that Shawkat does not teach administering the product for the same reasons as claimed. This is not persuasive as s discussed *supra*, a recitation of intended use must result in or structural difference between the claimed composition and the prior art composition.

Therefore, the rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medenica (US 5,653,981) for the reasons set forth in the previous Office action.

Medenica (US 5,653,981) teaches using an extract of *Nigella sativa* for increasing the immune system function. *Nigella sativa* has been found to help restore immune receptor cells in cancer patients. Medenica also teaches how to administer the extract of *Nigella sativa* such as intramuscular, subcutaneous, intravenous, tablet, capsule or suppositories or the like. Medenica does not teach the exact concentration of the claimed extract (column 3, lines 38-42; column 4, 13-15; column 5, lines 31-42). The dosage form of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the dosage form of each ingredient in order to best achieve the desired results. The reference also does not

specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Applicant's arguments filed July 1, 2005 have been fully considered but they are not persuasive.

Applicant argues that the Examiner never explicitly states a rejection of any claim that is based on Medenica in view of Shawkat. This is true since the Examiner *never* rejected "reference Medenica in view of Shawkat." The Examiner maintains separate rejections of Medenica accordingly. As discussed *supra*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). With regards to the dosage form or amount of a specific ingredient, one skilled in the art would be motivated to modify different dosage forms or amounts of a specific ingredient to see which form or amount would work the best in the invention as taught by the reference.

Therefore the rejection is proper and is maintained.

Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shawkat (US 5,648,089) for the reasons set forth in the previous Office action.

Shawkat (US 5,648,089) teaches using *Nigella sativa* in an oral herb composition to treat patients diagnosed with active Hepatitis-B and Hepatitis-C (column 1, lines 20-35, 60 and claim 1). The reference does not specifically teach the ingredients in the dosage forms claimed by Applicant. The dosage form of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the dosage form of each ingredient in order to best achieve the desired results. The reference also does not specifically teach the

ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results.

Applicant argues that the Examiner never explicitly states a rejection of any claim that is based on Medenica in view of Shawkat. This is true since the Examiner *never* rejected "reference Shawkat in view of Medenica." The Examiner maintains separate rejections of Medenica accordingly. As discussed *supra*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). With regards to the dosage form or amount of a specific ingredient, one skilled in the art would be motivated to modify different dosage forms or amounts of a specific ingredient to see which form or amount would work the best in the invention as taught by the reference.

Therefore the rejection is proper and is maintained.

Summary

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
8-30-05
SUSAN COE
PRIMARY EXAMINER